

K113788

MAR 16 2012

510(k) Summary (Rev 01)**(1) Submitter:**

NUXEN S.R.L..
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Contact person: Pablo Lagostena

Preparation Date: August 1, 2011

(2) Device Proprietary Information

Trade Name: DEFLEX ACRILATO

Common Name: Polymer for Injection of Denture Bases

Classification Name: Denture relining, repairing, or rebasing resin (21 CFR 872.3760, Product Code EBI)

(3) Predicate Devices

510(k) Number	Trade Name	Manufacturer
K053060	TCS unbreakable	Thermoplastic Comfort Systems, Inc.
K102874	Veracryl	New Stetic

(4) Device Description

Deflex Acrilato is a pigmented granulated polymethyl-methacrylate (PMMA) resin that belongs to the group of thermoplastic polymers which is used for the manufacturing of partial, complete and combined dentures.

The product is presented in pellets, packed in an aluminum canister (as a primary packaging), and then in a vacuum sealed aluminized plastic bag (as a secondary packaging).

The PMMA granules are pigmented so as to achieve aesthetic effects on the manufactured denture.

(5) Intended Use

This product is indicated for the manufacturing of bases of partial or full removable dentures, occlusal splints and night guards through heating and pneumatic injection of the material, following the Indications of Use that come with the product.

(6) Comparison to predicate devices

Deflex Acrilato is a thermoplastic injectable polymer that belong to the group of the PMMA. As no thermoplastic injectable PMMA could be identified as predicate; the properties of the material were divided into two groups and compared to different predicate devices (all of them having the same intended use), the first one sharing similar indications of use and mechanical properties and the second one sharing similar composition and chemical properties

Intended use, mechanical properties and indications of use have been compared to the following currently marketed thermoplastic injectable material:

510(k) Number	Trade Name	Manufacturer
K053060	TCS unbreakable	Thermoplastic Comfort Systems, Inc.

Intended use, chemical composition and chemical properties have been compared to the following currently marketed thermoplastic injectable material:

510(k) Number	Trade Name	Manufacturer
K102874	Veracryl	New Stetic

Finding that:

Comparison of Intended Use

- The two predicates and Deflex Acrilato have the same intended use

Comparison to TCS

- Deflex Acrilato and TCS have similar indications of use
- Both products show flexible and resilient behavior being DEFLEX ACRILATO more resistant than its predicate

Comparison to Veracryl

- Both materials have been characterized as poly methyl methacrylate
- Both materials show similar residual MMA monomer content
- Both materials show similar water absorption and solubility levels
- Deflex acrilato shows much lower solubility levels than its predicate, which is an indication of long term stability and inert behavior

Considering that both TCS and VERACRYL have essentially the same intended use of DEFLEX ACRILATO, that mechanical properties and indications of use are comparable to those of TCS and that chemical composition and chemical properties are comparable to those of VERACRYL, It is our conclusion that **Deflex Acrilato** is substantially equivalent to predicate devices in safety and effectiveness.

(7) Non Clinical Testing

The following tests have been carried out in order to demonstrate product's safety and effectiveness

TEST	Standard or Test Method applied
Material characterization	Internal laboratory method
Mechanical properties	EN 20795-1:2009 *
Residual MMA monomer content	EN 20795-1:2009 *
Water absorption	EN 20795-1:2009 *
Water solubility	EN 20795-1:2009 *

* equivalent to test method described in ANSI+ADA+12-2002+(R2008)

(8) Clinical Investigation

Clinical investigation is not required for this device in order to demonstrate its safety and effectiveness.

(9) Conclusion

NUXEN S.R.L. concludes that DEFLEX ACRILATO Resin for dental prostheses is substantially equivalent to its predicate devices. Based upon test data submitted, the product included in this submission can be safely and effectively used for manufacturing bases of partial removable or complete dentures through heating processes and pneumatic injection of the material, following the "indications of use" that come with the product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Nuxen S.R.L.
C/O Mr. Hernan Ilari
Consultant
IC INGENIERIA
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MAR 16 2012

Re: K113788
Trade/Device Name: DEFLEX ACRILATO
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI and MQC
Dated: March 12, 2012
Received: March 12, 2012

Dear Mr. Ilari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

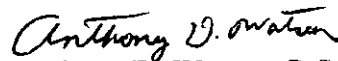
Page 2 – Mr. Hernan Ilari:

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113788

Device Name:

DEFLEX ACRILATO

Indications for Use:

This product is indicated for the manufacturing of bases of partial or full removable dentures, occlusal splints and night guards through heating and pneumatic injection of the material, following the Indications of Use that come with the product.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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